IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ORTHOPAEDIC HOSPITAL d/b/a Orthopaedic Institute For Children, Plaintiff, v. Aesculap Implant Systems, LLC, Defendants.	Civil Action No. _____ **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Orthopaedic Hospital d/b/a/ Orthopaedic Institute For Children ("Orthopaedic Hospital" or "Plaintiff"), by its undersigned attorneys, brings this action against Defendant Aesculap Implant Systems, LLC ("Aesculap" or "Defendant") as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of U.S. Patent No. 8,796,347 B2 (the "'347 Patent"), U.S. Patent No. 8,658,710 B2 (the "'710 Patent"), U.S. Patent No. 9,155,817 B2 (the "'817 Patent"), U.S. Patent No. 9,242,025 (the "'025 Patent"), and U.S. Patent No. 9,302,028 B2 (the "'028 Patent"), collectively referred to herein as the "Patents-In-Suit."

2. A true and correct copy of the '347 Patent is attached hereto as Exhibit 1.

3. A true and correct copy of the '710 Patent is attached hereto as Exhibit 2.

4. A true and correct copy of the '817 Patent is attached hereto as Exhibit 3.

5. A true and correct copy of the '025 Patent is attached hereto as Exhibit 4.

6. A true and correct copy of the '028 Patent is attached hereto as Exhibit 5.

THE PARTIES

7. Plaintiff Orthopaedic Hospital is a nonprofit public benefit corporation organized under the laws of the State of California doing business as Orthopaedic Institute for Children, with a principal place of business at 403 West Adams Blvd., Los Angeles, California 90007-2664.

8. Defendant Aesculap Implant Systems, LLC is a Delaware limited liability company with a principal place of business at 3773 Corporate Parkway, Center Valley, Pennsylvania 18034.

JURISDICTION AND VENUE

9. This is an action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code § 100 *et seq*.

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. Defendant, by itself or through its affiliates, agents, and/or partners, develops and manufactures orthopedic products, including the infringing products identified below, and markets and distributes such orthopedic products around the world, including in this Judicial District. Defendant has offered and continues to offer a full line of orthopedic implants for knee and hip replacements, as well as surgical instruments and techniques used therein. For example, Defendant has marketed Plasmafit® Acetabular Cup System and Vitelene® Insert, for which it obtained FDA approval in 2013, in this Judicial District.

12. Defendant's orthopedic products are used by orthopedic specialists, spine surgeons, and other healthcare professions in this Judicial District and throughout the world.

13. This Court has personal jurisdiction over Defendant because it is incorporated in Delaware and regularly conducts business in this Judicial District. Defendant has purposefully availed itself of the privilege of conducting activities within this Judicial District. Defendant's

activities in this Judicial District are continuous and systematic and give rise to the liabilities sued upon herein. More specifically, upon information and belief, Defendant's activities in this Judicial District have included, *inter alia*, selling and offering to sell infringing products in this Judicial District, marketing and advertising infringing products in this Judicial District, and inducing others to use infringing products in this Judicial District. Upon information and belief, Defendant does extensive business within the State of Delaware and earns substantial amounts of revenue through its contacts with this Judicial District. These activities far exceed the minimum requisite contacts.

14. Venue is proper as to Defendant under 28 U.S.C. § 1400(b) because Defendant is incorporated in this Judicial District.

ORTHOPAEDIC HOSPITAL AND ITS INNOVATIONS

15. Orthopaedic Hospital is an independent charitable organization that provides care for children with musculoskeletal disorders. Musculoskeletal disorders are characterized by chronic pain and limited mobility. The causes of musculoskeletal disorders in children range from birth defects to trauma caused by accidents and sports injuries.

16. Orthopaedic Hospital is the largest pediatric orthopedic program in the western United States with more than 70,000 patient visits in 2018. The Hospital's Orthopaedic Research Center has more than 30 clinicians/scientists focused on skeletal development, dysplasia and pediatric reconstruction.

17. Since its inception, Orthopaedic Hospital has been making a global impact in the field of pediatric orthopedics through medical education, research, and care.

18. Orthopaedic Hospital also expends considerable effort to advance the quality of materials used in the treatment of musculoskeletal disorders. In addition to seeing and treating tens of thousands of children per year that come through Orthopaedic Hospital's doors, Orthopaedic Hospital conducts scientific research aimed at improving orthopedic materials, implants, surgical instrumentation, and surgical techniques.

19. With that goal in mind, Orthopaedic Hospital researched and developed novel ultra-high molecular weight polyethylenes ("UHMWPE"), commonly used for making components of artificial joints, such as the acetabular cups used in artificial hip joints.

20. Orthopaedic surgeons may use UHMWPE implants to treat patients with permanent or progressive joint degeneration as a result of osteoarthritis, rheumatoid arthritis, trauma, or other joint disorders. For example, when the ball-and-socket joint of the hip is severely damaged, an orthopedic surgeon may suggest total hip replacement surgery. In a hip replacement surgery, for

example, the surgeon replaces the damaged portions of the hip joint with artificial parts designed to function like the original joint. The surgeon removes the damaged surface of a hip socket and inserts an artificial socket, called the acetabular component or cup. The surgeon then removes the head of the femur and hollows out the top of the femur before placing a metal rod, or femoral stem, into the bone. The surgeon attaches a ball to the rod and places the femur into the new socket. Because the femoral ball is in constant movement within the hip socket cup, various materials, including polyethylene, have been used to line the cup to facilitate movement. However, wear of those polyethylene components can be a significant problem.

21. Wear causes deterioration of the components and releases debris particles inside the body, which can lead to inflammation and loosening of the artificial joint components and even bone deterioration. Therefore, researchers have sought to develop a polyethylene material that is wear-resistant over time while maintaining important qualities such as fatigue strength, fracture toughness, and shear toughness.

22. Prior to 1999, orthopedic implants suffered from numerous problems.

23. When inserted into a human body, the polyethylene implants would wear, releasing microscopic polyethylene particles that would eat away bone near the implant.

24. In response, researchers started irradiating the implants to cause crosslinking within the polyethylene and improve the implant's wear-resistance. However, irradiation has unwanted side effects including generation of free radicals that bond with oxygen molecules they encounter in the air before implantation or in the body after implantation. Such oxidation, similar to rust, causes pitting, delamination or separation into layers, and fracture of the polyethylene implants.

25. Oxidation of the implant can contribute to fractures and complete failure in artificial knee and hip replacements.

26. Researchers applied heat, or thermal treatments, to improve oxidation resistance of implants. Such thermal treatments included remelting, or heating the implant above its melt temperature, and annealing, or heating the implant to just below its melt temperature.

27. These types of heat treatments, however, still weakened the implants, leading to damage.

28. To solve the problem of damage caused by oxidation, Orthopaedic Hospital researchers discovered that beginning with an oxidation-resistant polyethylene would enable improving the wear resistance using radiation-induced crosslinking, without the need for post-irradiation melting or annealing to remove free radicals.

29. This absence of a post-irradiation melting or annealing further simplified the manufacturing process and resulted in a greater resistance to cracking than if the polyethylene was melted or annealed to remove the free radicals.

30. The result of Orthopaedic Hospital's research culminated in the applications that yielded, and the inventions claimed in, the Patents-In-Suit.

THE PATENTS-IN-SUIT

31. The Patents-In-Suit teach that an implant can be rendered oxidation-resistant for example by adding one or more antioxidants, such as Vitamin E, to the polyethylene. The antioxidant scavenges free radicals and stabilizes them, preventing them from bonding with oxygen. As a result, the implant can be irradiated at a higher dose than typically used for conventional sterilization so as to increase crosslinking and improve wear resistance. Moreover, the patented method eliminates the need for a thermal treatment to extinguish free radicals created by the irradiation, which avoids weakening and deforming the implant through heating.

32. The Patents-In-Suit are each entitled "Oxidation-Resistant and Wear-Resistant Polyethylenes for Human Joint Replacements and Methods for Making Them" and are generally directed to methods for making wear-resistant and oxidation-resistant polyethylene orthopedic implants without thermally treating them to extinguish free radicals.

33. The inventors of the Patents-In-Suit are Dr. Harry A. McKellop and Dr. Fu-Wen Shen.

34. The '347 Patent was duly and legally issued on August 5, 2014, from U.S. Patent Application No. 10/258,762, which was filed on October 25, 2002, and claims priority to a U.S. Provisional Patent Application No. 60/200,525 filed on April 27, 2000.

35. Plaintiff is the owner of all rights, title and interest with respect to the '347 Patent.

36. The '710 Patent was duly and legally issued on February 25, 2014, from U.S. Patent Application 11/805,867, which was filed on May 24, 2007, as a continuation of U.S. Patent Application 10/258,762, filed on October 25, 2002—which yielded the '347 Patent—and claims priority to U.S. Provisional Patent Application No. 60/200,525, filed on April 27, 2000.

37. Plaintiff is the owner of all rights, title and interest with respect to the '710 Patent.

38. The '817 Patent was duly and legally issued on October 13, 2015, from U.S. Patent Application 14/566,084, which was filed on December 10, 2014, as a continuation of Application No. 14/489,069, filed on Sep. 17, 2014, which is a continuation of Application No. 14/258,553, filed on Apr. 25, 2014, which is a continuation of Application No. 10/258,762—which yielded the '347 Patent—and claims priority to U.S. Provisional Patent Application No. 60/200,525, filed on April 27, 2000.

39. Plaintiff is the owner of all rights, title and interest with respect to the '817 Patent.

40. The ’025 Patent was duly and legally issued on January 26, 2016, from U.S. Patent Application 14/489,069, which was filed on September 17, 2014, and claims priority through a series of continuation applications—which yielded the ’347 Patent—and claims priority to U.S. Provisional Patent Application No. 60/200,525, filed on April 27, 2000.

41. Plaintiff is the owner of all rights, title and interest with respect to the ’025 Patent.

42. The ’028 Patent was duly and legally issued on April 5, 2016 from U.S. Patent Application 14/262,553, which was filed on April 25, 2014 as a continuation of U.S. Patent Application 10/258,762, filed on October 25, 2002—which yielded the ’347 Patent—and claims priority to U.S. Provisional Patent Application No. 60/200,525, filed on April 27, 2000.

43. Plaintiff is the owner of all rights, title and interest with respect to the ’028 Patent.

44. The ’710 Patent and ’374 Patents were previously asserted against DePuy Orthopaedics (“DePuy”) in a litigation before the United States District Court for the Northern District of Indiana, styled as *Orthopaedic Hospital v. DePuy Orthopaedics, Inc.*, Civil Action No. 3:14-CV-00608, which was consolidated into Civil Action No. 3:12-CV-00299 (“the DePuy Litigation”).

45. In the DePuy Litigation action, Orthopaedic Hospital alleged that DePuy infringed the ’710 Patent and the ’347 Patent based on DePuy’s manufacturing and selling artificial knee systems made using a polyethylene material called AOX that leveraged the inventions claimed in the Patents-In-Suit.

46. In the context of the DePuy Litigation, DePuy filed petitions for *inter partes* review with the Patent Trial and Appeal Board (“PTAB”) challenging the claims of each of the ’710 and ’347 Patents, Nos. IPR2015-00510 and IPR2015-00512 respectively (“the DePuy IPRs”).

47. The PTAB denied both of the DePuy IPRs at the institution phase, finding that DePuy had not "established a reasonable likelihood of prevailing with respect to any of the challenged claims" as statutorily required for an IPR.

48. The PTAB also found that DePuy had not "established that a person of ordinary skill in the art would have had a sufficient reason, at the time of the invention, to irradiate the polyethylene implant material taught in the prior art at a radiation dose above 5 Mrad without also thermally treating the implant during or after the irradiation step."

49. The litigation against DePuy was subsequently voluntarily dismissed, by stipulation of the parties, pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(ii) on November 16, 2018.

50. The Patents-In-Suit were previously asserted against Globus Medical, Inc. ("Globus Medical") in a litigation before this Court, styled as *Orthopaedic Hospital v. Globus Medical, Inc.*, Civil Action No. 1:20-cv-00648-LPS (D. Del.) (the "Globus Medical Litigation").

51. In the Globus Medical Litigation, Orthopaedic Hospital alleged that Globus Medical infringed the Patents-in-Suit based on Globus Medical's (and formerly Stelkast, Inc.'s) manufacturing and selling hip and knee reconstruction products using a polyethylene material called EXp™ polyethylene that leveraged the inventions claimed in the Patents-In-Suit.

52. The litigation against Globus Medical was voluntarily dismissed pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(i) on July 1, 2020, after Orthopaedic Hospital and Globus Medical entered into a confidential settlement and license agreement.

53. The Patents-In-Suit are currently asserted against DJO Global, Inc. and DJO Finance LLC (collectively, "DJO") in a litigation before the United States District Court for the Southern District of California, styled as *Orthopaedic Hospital v. DJO Global, Inc. et al.*, Civil Action No. 3:19-cv-00970-JLS-AHG ("the DJO Litigation").

54. In the DJO Litigation, Orthopaedic Hospital alleges that DJO infringes the Patents-In-Suit based among other things on DJO's manufacturing and selling artificial knee, hip, shoulder, and elbow systems made using a polyethylene material called e+ that, upon information and belief, leverages the inventions claimed in the Patents-In-Suit.

DEFENDANT'S INFRINGEMENT

55. Aesculap is the 6th largest orthopaedic implant company in the world.

56. Aesculap offers a comprehensive suite of knee and hip implants and instruments that support minimally invasive surgery.

57. Aesculap markets its orthopaedic products to both surgeons and patients, and assists patients in locating surgeons who utilize its products, instruments, and techniques in joint reconstruction.

58. Upon information and belief, Aesculap leveraged Orthopaedic Hospital's patented inventions as part of its vitamin E blended polyethylene (referred to as "Vitelene®") that is offered by Defendant across its hip reconstruction and femoral head product lines.

59. Upon information and belief, Aesculap began manufacturing, selling and offering for sale, and instructing physicians in the use of products that incorporate the Vitelene® polyethylene as early as 2014.

60. Aesculap's Vitelene® polyethylene manufacturing process produces oxidation-resistant and wear-resistant components for implantation in a patient's body as part of a joint prosthesis.

61. Aesculap's Vitelene® polyethylene manufacturing process includes a step of blending vitamin E into GUR 1020 polyethylene.

> Vitelene insert is an ultra-high molecular weight polyethylene (UHMW-PE) blended with 1000 ppm (0.1% w/w) alpha-tocopherol (Vitamin E). The finished homogenous product conforms to ISO 5834-2.

62. Vitamin E is a known antioxidant.

63. Aesculap's vitamin E–blended polyethylene is oxidation resistant.

64. Aesculap's Vitelene® polyethylene manufacturing process includes a step of irradiating the implant material at a dose of about 75–80 kGy (equivalent to 7.5–8 Mrad) to form crosslinks in the polyethylene.

> Vitelene® is a highly crosslinked GUR 1020 polyethylene blended with vitamin E.
>
> Vitamin E provides long-term oxidation protection by binding free radicals through the release of H atoms. Polyethylene powder GUR 1020 is mixed with vitamin E (0.1 % - α-tocopherol) and pressed into sheets.
> Afterwards a total dose of 80 kGy electron beam radiation is applied to cross link the blank product.

65. Aesculap's Vitelene® polyethylene manufacturing process does not include a thermal treatment step during or after irradiation.

> Vitelene® needs no thermal treatment and has, therefore, balanced mechanical properties. It is characterized by wear and oxidation resistance.

66. Aesculap's Brochure No. 044302 is a marketing brochure generated and maintained by Aesculap in the ordinary course of its business entitled "Aesculap® Vitelene®: Vitamin E Stabilized Highly Crosslinked Polyethylene."

67. In Brochure No. 044302, Aesculap stated: "Vitelene® needs no thermal treatment."

68. In Brochure No. 044302, Aesculap stated: "By adding vitamin E a thermal treatment after irradiation is not necessary and the mechanical properties of Vitelene® can be preserved."

69. Brochure No. 044302 has been publicly available since 2013.

70. Brochure No. 044302 is currently available on the public-facing website of Aesculap's affiliate B Braun at https://www.bbraun.com/en/products/b0/vitelene.html.

71. Upon information and belief, Brochure No. 044302 is available on Aesculap's public-facing website.

72. Aesculap's affiliate B Braun's website states: "Vitelene® needs no thermal treatment and has, therefore, balanced mechanical properties." https://www.bbraun.com/en/products/b0/vitelene.html.

73. Aesculap's Brochure No. 045502 is a marketing brochure generated and maintained by Aesculap in the ordinary course of its business entitled "AESCULAP® Plasmafit®: Cementless Acetabular Cup System."

74. In Brochure No. 045502, Aesculap stated: "There is no post-irradiation thermal treatment necessary, hence no negative impact on mechanical properties is induced. Vitelene® needs no thermal treatment and has, therefore, balanced mechanical properties."

75. Brochure No. 045502 is currently available on the public-facing website of Aesculap's affiliate B Braun at https://www.bbraun.com/en/products/b0/vitelene.html.

76. Upon information and belief, Brochure No. 045502 is available on Aesculap's public-facing website.

77. Aesculap's DOC1169 is a marketing brochure generated and maintained by Aesculap in the ordinary course of its business entitled "Plasmafit™ PRO Acetabular System with Vitelene™ Liner: Feel the Fit."

78. In DOC1169, Aesculap stated: "The material does not need thermal treatment, such as remelting or annealing, and therefore has balanced mechanical properties and oxidative resistance."

79. Since 2014, Aesculap has made DOC1169 publicly available on its public-facing website.

80. DOC1169 is currently available on Aesculap's public-facing website at https://www.aesculapimplantsystems.com/content/dam/aesculap-us/us/website/aesculap-implant_systems/hp-section/ortho-product-pages/ortho-resources-pdfs/DOC1169-PlasmafitPRO-Brochure.pdf.

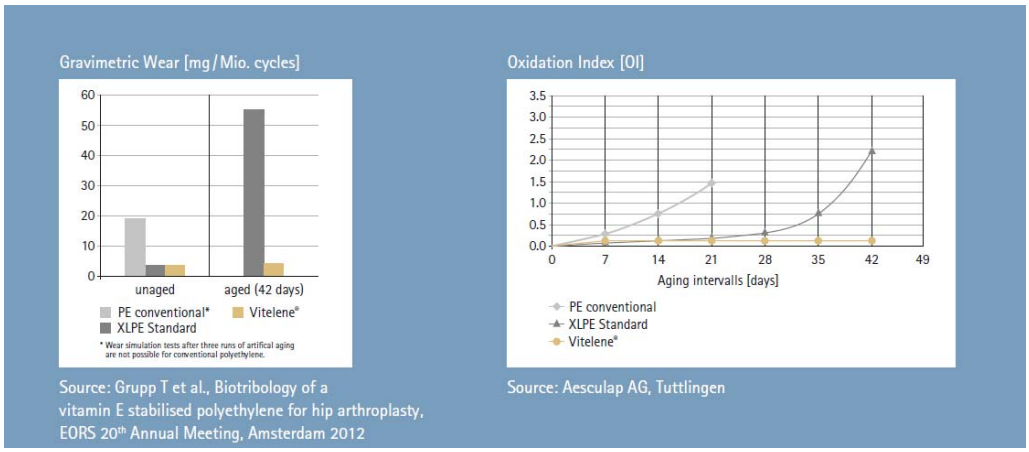
81. Upon information and belief, Aesculap requires that all of its marketing collateral goes through a rigorous collateral approval process.

82. Upon information and belief, Aesculap has adopted procedures to ensure that the contents of its marketing collateral are accurate.

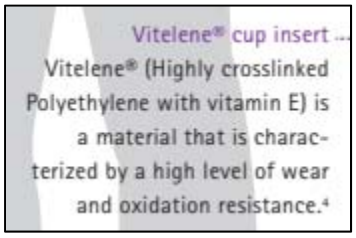
83. Aesculap's Vitelene® polyethylene manufacturing process includes a sterilizing step.

84. Aesculap's Vitelene® implant products are sterilized using ethylene oxide.

85. Aesculap's Vitelene® implant products are oxidation-resistant and wear-resistant.

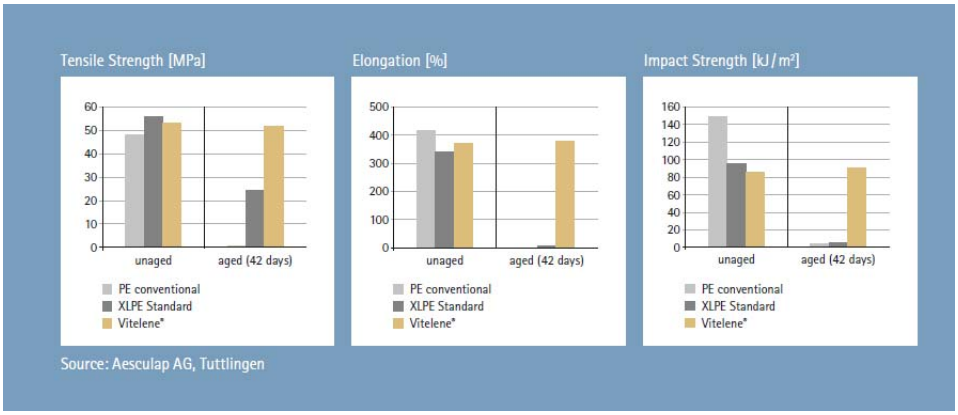


> Vitelene® needs no thermal treatment and has, therefore, balanced mechanical properties. It is characterized by wear and oxidation resistance.



> **The Integrity:** The vitamin E blended polyethylene liner provides a bearing surface with oxidative stability that maintains mechanical properties and resists wear.

86. The impact of oxygen exposure to Vitelene™ samples was evaluated by Aesculap in accelerated aging tests. These tests revealed that un-aged and aged Vitelene™ samples yielded substantially similar results, confirming that Vitelene™ is oxidation resistant.



The vitamin E insert has been shown to be more resistant to oxidation than conventional UHMWPE. Characterization of the oxidation indices of aged (ASTM F2003) and un-aged Vitelene measured according to ISO 5834-4 did not decrease. Further, Vitelene remains resistant to oxidation after 5 million cycles of wear as demonstrated in testing performed in accordance to ISO 14242-1 and ISO 1424-2.

87. In 2013, Aesculap received FDA clearance for its Plasmafit™ Pro Acetabular Cup System and Vitelene™ Insert.

88. Aesculap's Vitelene® polyethylene has been incorporated into the Excia™, Metha™, Prevision™, and Unisyn™ hip implant systems.

89. Aesculap's Vitelene® polyethylene has also been available as a component with the Biolox Option, Biolox Forte, Biolox Delta, and CoCrMo femoral heads.

90. Upon information and belief, Aesculap started selling and offering for sale Vitelene® implant products at least as early as 2014.

91. Aesculap provides healthcare professionals with resources to learn more about the use of and research surrounding the Vitelene® implant products, and provides educational, charitable, and research funding to healthcare professionals and medical academics.

92. Aesculap encourages physicians to use, and instructs physicians in the use of, Vitelene® implant products.

93. Aesculap provides physicians with written materials regarding the use of Vitelene® implant products, including instructions for use (IFUs) and surgical technique guides.

94. Leveraging Orthopaedic Hospital's patented innovation, Aesculap has generated and continues to generate revenue from the sale of Vitelene® implant products and related implant products and surgical tools in the United States and internationally.

Defendant's Notice of the Patents-in-Suit

95. Upon information and belief, Aesculap has had active and constructive knowledge of the '347 Patent and its related patent applications since at least as early as August 5, 2014, the date on which the '347 Patent issued.

96. Upon information and belief, Aesculap has had active and constructive knowledge of the '710 Patent and its related patent applications since at least as early as February 25, 2014, the date on which the '710 Patent issued.

97. Upon information and belief, Aesculap has had active and constructive knowledge of the '817 Patent and its related patent applications since at least as early as October 13, 2015, the date on which the '817 Patent issued.

98. Upon information and belief, Aesculap has had active and constructive knowledge of the '025 Patent and its related patent applications since at least as early as January 26, 2016, the date on which the '025 Patent issued.

99. Upon information and belief, Aesculap has had active and constructive knowledge of the '028 Patent and its related patent applications since at least as early as April 5, 2016, the date on which the '028 Patent issued.

100. Upon information and belief, Aesculap has a practice of investigating the patent landscape before launching new products.

101. Orthopaedic Hospital's international patent application PCT/US01/13839 was published as WO 01/80778 on November 1, 2001.

102. The applications that yielded the ’347 and ’710 Patents were published by the U.S. Patent and Trademark Office as U.S. Patent Pub. Nos. 2003/0212161 and 2007/0293647 on November 13, 2003, and December 20, 2007, respectively.

103. Upon information and belief, Aesculap had knowledge of at least one or more of WO 01/80778 and/or U.S. Patent Pub. Nos. 2003/0212161 and/or 2007/0293647 prior to launching its Vitelene® products.

104. Upon information and belief, Aesculap identifies DePuy as one of its competitors with respect to its surgical implant products.

105. Upon information and belief, Aesculap has monitored DePuy’s sales and marketing of competing products, including those products that compete with the products accused of infringing the Patents-In-Suit, as well as DePuy’s public filings and any litigation relating to such products.

106. Upon information and belief, Aesculap had notice of the Patents-in-Suit and/or the application(s) that yielded such patents because Orthopaedic Hospital’s complaint in the DePuy Litigation for infringement of the ’347 and ’710 Patents was filed on February 24, 2014. The complaint itself was publicly available, and Orthopaedic Hospital’s filing was reported in the press.

107. Upon information and belief, Aesculap had notice of the Patents-in-Suit and/or the application(s) that yielded such patents because, during the pendency of the DePuy Litigation, DePuy publicly disclosed, including in filings with the SEC, that it was involved in a patent litigation in which its AOX products were accused of infringing the ’347 and ’710 Patents.

108. Upon information and belief, Aesculap identifies DJO as one of its competitors with respect to its surgical implant products.

109. Upon information and belief, Aesculap monitors DJO's sales and marketing of competing products, including those products that compete with the products accused of infringing the Patents-In-Suit, as well as DJO's public filings and any litigation relating to such products.

110. Upon information and belief, Aesculap had notice of the Patents-in-Suit and/or the application(s) that yielded such patents because Orthopaedic Hospital's complaint in the DJO Litigation for infringement of the Patents-In-Suit was filed on May 23, 2019. The complaint itself was publicly available, and Orthopaedic Hospital's filing was reported in the press.

111. Additionally, Aesculap had actual knowledge of the Patents-in-Suit at least as of July 26, 2019, the date upon which a letter was sent to Aesculap Implant Systems, LLC notifying Aesculap of its infringement of the Patents-in-Suit.

FIRST CAUSE OF ACTION

(Direct Infringement of the '347 Patent under 35 U.S.C. § 271(a))

112. Orthopaedic Hospital incorporates the foregoing allegations as if fully realleged and restated herein.

113. The '347 Patent is valid and enforceable, as it was duly and legally issued by the United States Patent and Trademark Office ("USPTO").

114. Upon information and belief, in violation of 35 U.S.C. § 271(a), Aesculap has infringed and continues to infringe at least one claim of the '347 Patent, literally and/or under the doctrine of equivalents, by practicing and/or directing and controlling the practice of a method that satisfies one or more claim(s) of the '347 Patent when making and/or directing and controlling the making of Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) in the United States.

115. Specifically, Defendant is responsible for the performance of each step of Claim 1 of the '347 Patent when it manufactures and/or directs and controls the manufacture of any of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof).

116. For example, each step of Claim 1 of the '347 Patent is performed when a Vitilene® insert implant for use with the Plasmafit™ Pro Acetabular System is manufactured, which, for purposes of this Complaint, will be treated as representative of the Vitelene® implant products and Vitelene® polyethylene component(s) thereof.

117. Claim 1 of the '347 Patent recites the following:

> **[Preamble]** A method for producing a wear-resistant and oxidation resistant medical implant of a joint prosthesis, said method comprising the steps of:
>
> **(I)** providing an oxidation-resistant medical implant of a joint prosthesis comprising a polyethylene component; and

> **(II)** irradiating the oxidation-resistant medical implant at a radiation dose of above 5 Mrad to about 25 Mrad so as to crosslink the implant thereby improving its wear resistance, without thermally treating the implant to extinguish free radicals in the irradiated and crosslinked implant during or subsequent to irradiating the oxidation-resistant implant;
>
> wherein the oxidation-resistant implant contains an antioxidant rendering it resistant to oxidation caused by free radicals generated by the irradiation of step (II).

Claim 1, Preamble

118. To the extent the preamble of Claim 1 of the '347 Patent is a limitation, upon information and belief, Defendant's method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component satisfies such limitation because it produces a wear-resistant and oxidation-resistant medical implant of a joint prosthesis.

119. Specifically, the Vitelene® liner provides a bearing surface of a hip prosthesis with oxidative stability that maintains mechanical properties and resists wear.

> **The Integrity:** The vitamin E blended polyethylene liner provides a bearing surface with oxidative stability that maintains mechanical properties and resists wear.

Claim 1, Step I

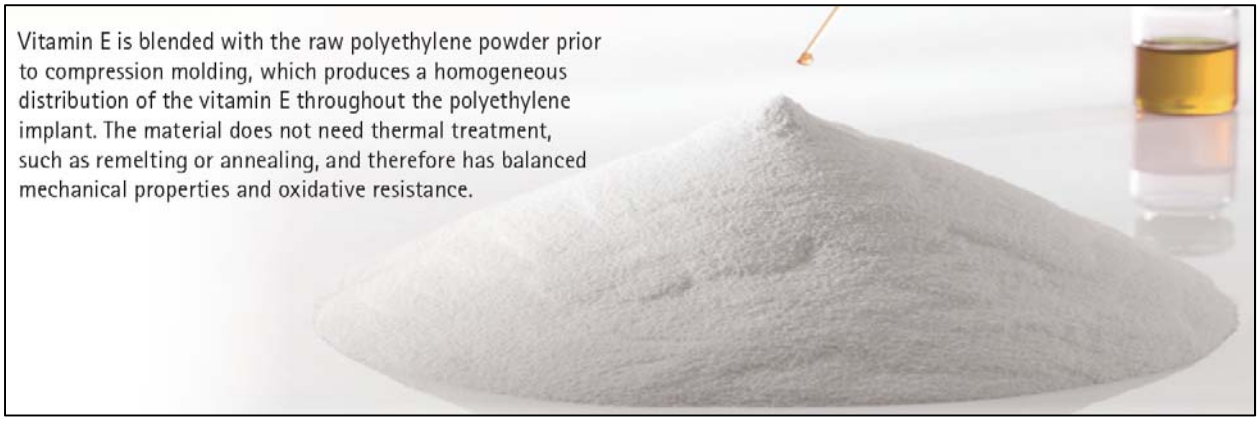
120. Upon information and belief, Defendant's method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component satisfies Step I of Claim 1 of the '347 Patent, because the method comprises a step of providing an oxidation-resistant medical implant of a joint prosthesis comprising a polyethylene component.

121. Specifically, Vitamin E is blended with raw polyethylene powder prior to compression molding. The result is a polyethylene material intended for ultimate implantation

into a patient's body in the form of an acetabular cup liner component of a hip prosthesis. The component is comprised of polyethylene. And the component is oxidation-resistant.

122. Aesculap has stated: "Vitamin E is blended with the raw polyethylene powder prior to compression molding, which produces a homogeneous distribution of the vitamin E throughout the polyethylene implant."

123. And Aesculap has state: "The material … has balanced mechanical properties and oxidative resistance."



Claim 1, Step II

124. Upon information and belief, Defendant's method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component satisfies Step II of Claim 1 of the '347 Patent, because the method comprises a step of irradiating the medical implant at a radiation dose of above 5 Mrad to about 25 Mrad so as to crosslink the implant thereby improving its wear resistance, without thermally treating the implant to extinguish free radicals in the irradiated and crosslinked implant during or subsequent to irradiating the oxidation-resistant implant.

125. Specifically, the implant is irradiated at a radiation dose of 7.5 or 8.0 Mrad.

126. Aesculap has stated that "a total dose of 80kGy [equivalent to 8.0 Mrad] electron beam radiation is applied to cross link the blank product."

127. Elsewhere, in for example a 510K submission to the FDA (K122783) and in its instructions for use (IFU), Aesculap has referred to the implant as "a highly crosslinked (β-75 kGy [equivalent to 7.5 Mrad]) ultra-high molecular weight polyethylene (UHMW-PE) vitamin E insert."

128. Aesculap has stated: "Vitelene showed an 89% reduction in wear compared to conventional polyethylene after accelerated aging testing per ASTM F2003."

129. Aesculap has stated: "The material does not need thermal treatment, such as remelting or annealing, and therefore has balanced mechanical properties and oxidative resistance."

130. And Aesculap has further stated that "by adding vitamin E a thermal treatment after irradiation is not necessary and the mechanical properties of Vitelene® can be preserved."

131. Indeed, Aesculap has explained that "Vitamin E provides long-term oxidative stability and high mechanical integrity by grafting onto the polyethylene chain during the crosslinking process in order to eliminate any remaining free radicals."

Claim 1, Step II (wherein clause)

132. Upon information and belief, Defendant's method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component further satisfies the wherein clause of Step II of Claim 1 of the '347 Patent, because the Vitelene® component contains an antioxidant rendering it resistant to oxidation caused by free radicals generated by the irradiation of step (II).

133. Specifically, each Vitelene® component contains α-Tocopherol, a type of vitamin E (an antioxidant). Blended with the polyethylene, the α-Tocopherol renders the Vitelene® component resistant to oxidation caused by free radicals generated by the irradiation of step (II).

134. Aesculap has stated that Vitelene® is "a highly crosslinked polyethelene blended with vitamin E," and "Vitamin E provides long-term oxidative stability and high mechanical integrity by grafting onto the polyethylene chain during the crosslinking process in order to eliminate any free radicals."

135. Plaintiff has been and continues to be injured monetarily and otherwise by Defendant's direct infringement of the '347 Patent in violation of 35 U.S.C. § 271. Defendant is therefore liable to Plaintiff for the damages suffered by Plaintiff.

136. By this action, Plaintiff seeks recovery of its damages pursuant to 35 U.S.C. § 284, including, without limitation, a reasonable royalty.

137. As further detailed above, Defendant has had active and constructive notice of the '347 Patent since at least as early as 2014. Accordingly, Defendant has known or should have known that the manufacture of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '347 Patent no later than August 5, 2014, the date on which the '347 Patent issued.

138. Alternatively, as further detailed above, Aesculap has had active and constructive notice of the '347 Patent since at least as early as February 2014. Accordingly, Defendant has known or should have known that the manufacture of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '347 Patent no later than February 2014.

139. At minimum, Aesculap had actual notice that its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringe one or more claims of the '347 Patent at least as of July 26, 2019.

140. Upon information and belief, Defendant's infringement of the '347 Patent has been and continues to be willful. Despite its knowledge of the '347 Patent and its infringement, Defendant has and continues to make, use, offer for sale, and sell the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) in the United States. Accordingly, Plaintiff is entitled to increased damages under 35 U.S.C. § 284 and to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

SECOND CAUSE OF ACTION

(Infringement of the '347 Patent under 35 U.S.C. § 271(g))

141. Orthopaedic Hospital incorporates the foregoing allegations as if fully realleged and restated herein.

142. Upon information and belief, in violation of 35 U.S.C. § 271(g), Defendant has directly infringed and continues to infringe, without authority, consent, right, or license, the '347 Patent by offering to sell, selling, or using within the United States the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) that are made by a process patented in the '347 Patent during the term of the patent.

143. Specifically, and as further detailed above, each of the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) is made by a process that comprises at least each step of Claim 1 of the '347 Patent.

144. Accordingly, Defendant's offers for sale, sales, and use of such Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) are infringing under § 271(g).

145. Plaintiff has been injured and continues to be injured monetarily and otherwise by Defendant's direct infringement of the '347 Patent in violation of 35 U.S.C. § 271(g). Defendant is therefore liable to Plaintiff for the damages suffered by Plaintiff.

146. By this action, Plaintiff seeks recovery of its damages pursuant to 35 U.S.C. § 284, including, without limitation, a reasonable royalty.

147. As further detailed above, Defendant has had active and constructive notice of the '347 Patent since at least as early as 2014. Accordingly, Defendant has known or should have known that the sale of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '347 Patent no later than August 5, 2014, the date on which the '347 Patent issued.

148. Alternatively, as further detailed above, Defendant has had active and constructive notice of the '347 Patent since at least as early as May 2019. Accordingly, Defendant has known or should have known that the sale of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '347 Patent no later than May 2019.

149. At minimum, Defendant had actual notice that the sale of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '347 Patent at least as of July 26, 2019.

150. Upon information and belief, Defendant's infringement of the '347 patent has been and continues to be willful. Despite its knowledge of the '347 Patent and its infringement, Defendant has and continues to use, offer for sale, and sell within the United States the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) which are made by a process patented in the '347 Patent during the term of the patent. Accordingly, Plaintiff is entitled to

increased damages under 35 U.S.C. § 284 and to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

THIRD CAUSE OF ACTION

(Induced Infringement of the '347 Patent under 35 U.S.C. § 271(b))

151. Orthopaedic Hospital incorporates the foregoing allegations as if fully realleged and restated herein.

152. Upon information and belief, in violation of 35 U.S.C. § 271(b), Defendant has indirectly infringed and is still indirectly infringing the '347 Patent by actively inducing infringement of the '347 Patent.

153. Defendant, with knowledge that the manufacturing of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) are made by a process patented by the '347 Patent, has induced and continues to induce its customers (such as physicians) and end users (such as patients) to directly infringe the '347 Patent by, for example, specifically instructing such individuals to buy and use the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) within the United States.

154. As further detailed above, upon information and belief, Defendant has had active and constructive knowledge of the '347 Patent and its related patent applications since at least as early as 2014. Accordingly, Defendant has known, should have known or has been willfully blind to the fact that the manufacture of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '347 Patent no later than August 5, 2014, the date on which the '347 Patent issued.

155. Alternatively, as further detailed above, Defendant has had active and constructive notice of the '347 Patent since at least as early as May 2019. Accordingly, Defendant has known,

should have known or has been willfully blind to the fact that the manufacture of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '347 Patent no later than May 2019.

156. At minimum, Defendant had actual notice that its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringe one or more claims of the '347 Patent at least as of July 26, 2019.

157. Upon information and belief, Defendant's customers (such as orthopaedic surgeons) and end users (such as patients) directly infringe the '347 Patent when they use within the United States the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof), which are made by a process patented in the '347 Patent during the term of the patent.

158. For example, Defendant advertises, and provides pictures and catalogue information about, the Vitelene® implant products on its website for healthcare professionals and patients alike.

159. Defendant further provides instructions for use (IFUs) for its Vitalene implant products on its website.

160. Defendant also provides resources for patients to find surgeons who utilize the Vitelene® implant products.

161. Plaintiff has been injured and continues to be injured monetarily and otherwise by Defendant's indirect infringement of the '347 Patent in violation of 35 U.S.C. § 271(b). Defendant is therefore liable to Plaintiff for the damages suffered by Plaintiff.

162. By this action, Plaintiff seeks recovery of its damages pursuant to 35 U.S.C. § 284, including, without limitation, a reasonable royalty.

163. Upon information and belief, Defendant's continuing acts of induced infringement are willful, entitling Plaintiff to increased damages under 35 U.S.C. § 284 and to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

FOURTH CAUSE OF ACTION

(Direct Infringement of the '710 Patent under 35 U.S.C. § 271(a))

164. Orthopaedic Hospital incorporates the foregoing allegations as if fully realleged and restated herein.

165. The '710 Patent is valid and enforceable, as it was duly and legally issued by the USPTO.

166. Upon information and belief, in violation of 35 U.S.C. § 271(a), Aesculap has infringed and continues to infringe at least one claim of the '710 Patent, literally and/or under the doctrine of equivalents, by practicing and/or directing and controlling the practice of a method that satisfies one or more claim(s) of the '710 Patent when making and/or directing and controlling the making of Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) in the United States.

167. Specifically, Defendant is responsible for the performance of each step of Claim 1 of the '710 Patent when it manufactures and/or directs and controls the manufacture of any of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof).

168. For example, each step of Claim 1 of the '710 Patent is performed when a Vitilene™ polyethylene liner for the Plasmafit™ Pro Acetabular System is manufactured.

169. Exemplary independent Claim 1 of the '710 Patent recites the following:

> **[Preamble]** A method for producing a wear-resistant and oxidation resistant medical implant of a joint prosthesis, said method comprising the steps of:

> **(I)** providing an oxidation-resistant medical implant of a joint prosthesis comprising a polyethylene component; and
>
> **(II)** irradiating the oxidation-resistant medical implant at a radiation dose of above 5 Mrad to about 25 Mrad so as to crosslink the implant thereby improving its wear resistance, without thermally treating the implant to extinguish free radicals in the irradiated and crosslinked implant during or subsequent to irradiating the oxidation-resistant implant;
>
> wherein the oxidation-resistant implant contains an antioxidant rendering it resistant to oxidation caused by free radicals generated by the irradiation of step (II); and the irradiated oxidation-resistant implant possesses the characteristics of: a degree of swelling of between about 1.7 to about 3.6; a molecular weight between crosslinks of between about 400 to about 3,500 g/mol; and a gel content of between about 95% to about 99%.

Claim 1, Preamble

170. To the extent the preamble of Claim 1 of the ’710 Patent is a limitation, upon information and belief, Defendant’s method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component satisfies such limitation because it produces a wear-resistant and oxidation-resistant medical implant of a joint prosthesis.

171. Specifically, the Vitelene® liner provides a bearing surface of a hip prosthesis with oxidative stability that maintains mechanical properties and resists wear.

Claim 1, Step I

172. Upon information and belief, Defendant’s method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component satisfies Step I of Claim 1 of the ’710 Patent, because the method comprises a step of providing an oxidation-resistant medical implant of a joint prosthesis comprising a polyethylene component.

173. Specifically, Vitamin E is blended with raw polyethylene powder prior to compression molding. The result is a polyethylene material intended for ultimate implantation into a patient's body in the form of an acetabular cup liner component of a hip prosthesis. The component is comprised of polyethylene. And the component is oxidation-resistant.

Claim 1, Step II

174. Upon information and belief, Defendant's method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component satisfies Step II of Claim 1 of the '710 Patent, because the method comprises a step of irradiating the medical implant at a radiation dose of above 5 Mrad to about 25 Mrad so as to crosslink the implant thereby improving its wear resistance, without thermally treating the implant to extinguish free radicals in the irradiated and crosslinked implant during or subsequent to irradiating the oxidation-resistant implant.

Claim 1, Step II (wherein clause)

175. Upon information and belief, Defendant's method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component further satisfies the wherein clause of Step II of Claim 1 of the '710 Patent, because the Vitelene® component contains an antioxidant rendering it resistant to oxidation caused by free radicals generated by the irradiation of step (II).

176. Specifically, each Vitelene® component contains α-Tocopherol, a type of vitamin E (an antioxidant). Blended with the polyethylene, the α-Tocopherol renders the Vitelene® component resistant to oxidation caused by free radicals generated by the irradiation of step (II).

177. Upon information and belief, Defendant's method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component further satisfies the wherein clause of Step II of Claim 1 of the '710 Patent, because, upon information and belief, the irradiated Vitelene® component possesses a degree of swelling of between about 1.7 to about 3.6.

178. Upon information and belief, Defendant's method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component further satisfies the wherein clause of Step II of Claim 1 of the '710 Patent, because, upon information and belief, the irradiated Vitelene® component possesses a molecular weight between crosslinks of between about 400 to about 3,500 g/mol.

179. Upon information and belief, Defendant's method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component further satisfies the wherein clause of Step II of Claim 1 of the '710 Patent, because, upon information and belief, the irradiated Vitelene® component possesses a gel content of between about 95% to about 99%.

180. Plaintiff has been and continues to be injured monetarily and otherwise by Defendant's direct infringement of the '710 Patent in violation of 35 U.S.C. § 271. Defendant is therefore liable to Plaintiff for the damages suffered by Plaintiff.

181. By this action, Plaintiff seeks recovery of its damages pursuant to 35 U.S.C. § 284, including, without limitation, a reasonable royalty.

182. As further detailed above, Defendant has had active and constructive notice of the '710 Patent since at least as early as 2014. Accordingly, Defendant has known or should have known that the manufacture of its Vitelene® implant products (and Vitelene® polyethylene

component(s) thereof) infringes one or more claims of the '710 Patent no later than February 25, 2014, the date on which the '710 Patent issued.

183. Alternatively, as further detailed above, Defendant has had active and constructive notice of the '710 Patent since at least as early as May 2019. Accordingly, Defendant has known or should have known that the manufacture of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '710 Patent no later than May 2019.

184. At minimum, Defendant had actual notice that its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringe one or more claims of the '710 Patent at least as of July 26, 2019.

185. Upon information and belief, Defendant's infringement of the '710 Patent has been and continues to be willful. Despite its knowledge of the '710 Patent and its infringement, Defendant has and continues to make, use, offer for sale, and sell the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) in the United States. Accordingly, Plaintiff is entitled to increased damages under 35 U.S.C. § 284 and to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

FIFTH CAUSE OF ACTION

(Infringement of the '710 Patent under 35 U.S.C. § 271(g))

186. Orthopaedic Hospital incorporates the foregoing allegations as if fully realleged and restated herein.

187. Upon information and belief, in violation of 35 U.S.C. § 271(g), Defendant has directly infringed and continues to infringe, without authority, consent, right, or license, the '710 Patent by offering to sell, selling, or using within the United States the Vitelene® implant products

(and Vitelene® polyethylene component(s) thereof) which are made by a process patented in the '710 Patent during the term of the patent.

188. Specifically, and as further detailed above, each of the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) is made by a process that comprises at least each step of Claim 1 of the '710 Patent.

189. Accordingly, Defendant's offers for sale, sales, and use of such Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) are infringing under § 271(g).

190. Plaintiff has been injured and continues to be injured monetarily and otherwise by Defendant's direct infringement of the '710 Patent in violation of 35 U.S.C. § 271(g). Defendant is therefore liable to Plaintiff for the damages suffered by Plaintiff.

191. By this action, Plaintiff seeks recovery of its damages pursuant to 35 U.S.C. § 284, including, without limitation, a reasonable royalty.

192. As further detailed above, Defendant has had active and constructive notice of the '710 Patent since at least as early as 2014. Accordingly, Defendant has known or should have known that the sale of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '710 Patent no later than February 25, 2014, the date on which the '710 Patent issued.

193. Alternatively, as further detailed above, Defendant has had active and constructive notice of the '710 Patent since at least as early as May 2019. Accordingly, Defendant has known or should have known that the sale of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '710 Patent no later than May 2019.

194. At minimum, Defendant had actual notice that the sale of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringe one or more claims of the '710 Patent at least as of July 26, 2019.

195. Upon information and belief, Defendant's infringement of the '710 patent has been and continues to be willful. Despite its knowledge of the '710 Patent and its infringement, Defendant has and continues to sell, offer for sale, and use within the United States the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) which are made by a process patented in the '710 Patent during the term of the patent. Accordingly, Plaintiff is entitled to increased damages under 35 U.S.C. § 284 and to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

SIXTH CAUSE OF ACTION

(Induced Infringement of the '710 Patent under 35 U.S.C. § 271(b))

196. Orthopaedic Hospital incorporates the foregoing allegations as if fully realleged and restated herein.

197. Upon information and belief, in violation of 35 U.S.C. § 271(b), Defendant has indirectly infringed and is still indirectly infringing the '710 Patent by actively inducing infringement of the '710 Patent.

198. Defendant, with knowledge that the manufacturing of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) are made by a process patented by the '710 Patent, has induced and continues to induce its customers (such as physicians) and end users (such as patients) to directly infringe the '710 Patent by, for example specifically instructing such individuals to use the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) within the United States.

199. As further detailed above, Defendant has had active and constructive notice of the '710 Patent since at least as early as 2014. Accordingly, Defendant has known, should have known or has been willfully blind to the fact that the manufacture of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '710 Patent no later than February 25, 2014, the date on which the '710 Patent issued.

200. Alternatively, as further detailed above, Defendant has had active and constructive notice of the '710 Patent since at least as early as May 2019. Accordingly, Defendant has known, should have known or has been willfully blind to the fact that the manufacture of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '710 Patent no later than May 2019.

201. At minimum, Defendant had actual notice that its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringe one or more claims of the '710 Patent at least as of July 26, 2019.

202. Upon information and belief, Defendant's customers (such as orthopedic surgeons) and end users (such as patients) directly infringe the '710 Patent when they use within the United States the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) which are made by a process patented in the '710 Patent during the term of the patent.

203. For example, Defendant advertises, and provides pictures and catalogue information about, the Vitelene® implant products on its website for healthcare professionals and patients alike.

204. Defendant also provides a resource for patients to find surgeons who utilize the Vitelene® implant products.

205. Plaintiff has been injured and continues to be injured monetarily and otherwise by Defendant's indirect infringement of the '710 Patent in violation of 35 U.S.C. § 271(b). Defendant is therefore liable to Plaintiff for the damages suffered by Plaintiff.

206. By this action, Plaintiff seeks recovery of its damages pursuant to 35 U.S.C. § 284, including, without limitation, a reasonable royalty.

207. Upon information and belief, Defendant's continuing acts of induced infringement are willful, entitling Plaintiff to increased damages under 35 U.S.C. § 284 and to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

SEVENTH CAUSE OF ACTION

(Direct Infringement of the '817 Patent under 35 U.S.C. § 271(a))

208. Orthopaedic Hospital incorporates the foregoing allegations as if fully realleged and restated herein.

209. The '817 Patent is valid and enforceable, as it was duly and legally issued by the USPTO.

210. Upon information and belief, in violation of 35 U.S.C. § 271(a), Aesculap has infringed and continues to infringe at least one claim of the '817 Patent, literally and/or under the doctrine of equivalents, by practicing and/or directing and controlling the practice of a method that satisfies one or more claim(s) of the '817 Patent when making and/or directing and controlling the making of Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) in the United States.

211. Specifically, Defendant is responsible for the performance of each step of Claim 1 of the '817 Patent when it manufactures and/or directs and controls the manufacture of any of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof).

212. For example, each step of Claim 1 of the ’817 Patent is performed when a Vitilene™ polyethylene liner for the Plasmafit™ Pro Acetabular System is manufactured.

213. Exemplary independent Claim 1 of the ’817 Patent recites the following:

> **[Preamble]** A method for producing a wear-resistant and oxidation resistant medical implant of a joint prosthesis, said method comprising the steps of:
>
> **(I)** providing an oxidation-resistant medical implant of a joint prosthesis comprising a polyethylene component; and
>
> **(II)** irradiating the oxidation-resistant medical implant at a radiation dose of above 5 Mrad so as to crosslink the implant thereby improving its wear resistance, without thermally treating the implant to extinguish free radicals in the irradiated and crosslinked implant during or subsequent to irradiating the oxidation-resistant implant,
>
> wherein the oxidation-resistant implant is highly resistant to oxidation caused by free radicals generated by the irradiation of step (II).

Claim 1, Preamble

214. To the extent the preamble of Claim 1 of the ’817 Patent is a limitation, upon information and belief, Defendant’s method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component satisfies such limitation because it produces a wear-resistant and oxidation-resistant medical implant of a joint prosthesis.

215. Specifically, the Vitelene® liner provides a bearing surface of a hip prosthesis with oxidative stability that maintains mechanical properties and resists wear.

Claim 1, Step I

216. Upon information and belief, Defendant’s method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component

satisfies Step I of Claim 1 of the ’817 Patent, because the method comprises a step of providing an oxidation-resistant medical implant of a joint prosthesis comprising a polyethylene component.

217. Specifically, Vitamin E is blended with raw polyethylene powder prior to compression molding. The result is a polyethylene material intended for ultimate implantation into a patient’s body in the form of an acetabular cup liner component of a hip prosthesis. The component is comprised of polyethylene. And the component is oxidation-resistant.

Claim 1, Step II

218. Upon information and belief, Defendant’s method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component satisfies Step II of Claim 1 of the ’817 Patent, because the method comprises a step of irradiating the medical implant at a radiation dose of above 5 Mrad so as to crosslink the implant thereby improving its wear resistance, without thermally treating the implant to extinguish free radicals in the irradiated and crosslinked implant during or subsequent to irradiating the oxidation-resistant implant.

Claim 1, Step II (wherein clause)

219. Upon information and belief, Defendant’s method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component further satisfies the wherein clause of Step II of Claim 1 of the ’817 Patent, because the Vitelene® component contains an antioxidant rendering it resistant to oxidation caused by free radicals generated by the irradiation of step (II).

220. Specifically, each Vitelene® component contains α-Tocopherol, a type of vitamin E (an antioxidant). Blended with the polyethylene, the α-Tocopherol renders the Vitelene® component resistant to oxidation caused by free radicals generated by the irradiation of step (II).

221. Plaintiff has been and continues to be injured monetarily and otherwise by Defendant's direct infringement of the '817 Patent in violation of 35 U.S.C. § 271. Defendant is therefore liable to Plaintiff for the damages suffered by Plaintiff.

222. By this action, Plaintiff seeks recovery of its damages pursuant to 35 U.S.C. § 284, including, without limitation, a reasonable royalty.

223. As further detailed above, Defendant has had active and constructive notice of the '817 Patent since at least as early as 2015. Accordingly, Defendant has known or should have known that the manufacture of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '817 Patent no later than October 13, 2015, the date on which the '817 Patent issued.

224. Alternatively, as further detailed above, Defendant has had active and constructive notice of the '817 Patent since at least as early as May 2019. Accordingly, Defendant has known or should have known that the manufacture of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '817 Patent no later than May 2019.

225. At minimum, Defendant had actual notice that its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringe one or more claims of the '817 Patent at least as of July 26, 2019.

226. Upon information and belief, Defendant's infringement of the '817 Patent has been and continues to be willful. Despite its knowledge of the '817 Patent and its infringement,

Defendant has and continues to make, use, offer for sale, and sell the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) in the United States. Accordingly, Plaintiff is entitled to increased damages under 35 U.S.C. § 284 and to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

EIGHTH CAUSE OF ACTION

(Infringement of the '817 Patent under 35 U.S.C. § 271(g))

227. Orthopaedic Hospital incorporates the foregoing allegations as if fully realleged and restated herein.

228. Upon information and belief, in violation of 35 U.S.C. § 271(g), Defendant has directly infringed and continues to infringe, without authority, consent, right, or license, the '817 Patent by offering to sell, selling, or using within the United States the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) which are made by a process patented in the '817 Patent during the term of the patent.

229. Specifically, and as further detailed above, each of the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) is made by a process that comprises at least each step of Claim 1 of the '817 Patent.

230. Accordingly, Defendant's offers for sale, sales, and use of such Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) are infringing under § 271(g).

231. Plaintiff has been injured and continues to be injured monetarily and otherwise by Defendant's direct infringement of the '817 Patent in violation of 35 U.S.C. § 271(g). Defendant is therefore liable to Plaintiff for the damages suffered by Plaintiff.

232. By this action, Plaintiff seeks recovery of its damages pursuant to 35 U.S.C. § 284, including, without limitation, a reasonable royalty.

233. As further detailed above, Defendant has had active and constructive notice of the '817 Patent since at least as early as 2015. Accordingly, Defendant has known or should have known that the sale of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '817 Patent no later than October 13, 2015, the date on which the '817 Patent issued.

234. Alternatively, as further detailed above, Defendant has had active and constructive notice of the '817 Patent since at least as early as May 2019. Accordingly, Defendant has known or should have known that the sale of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '817 Patent no later than May 2019.

235. At minimum, Defendant had actual notice that the sale of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '817 Patent at least as of July 26, 2019.

236. Upon information and belief, Defendant's infringement of the '817 patent has been and continues to be willful. Despite its knowledge of the '817 Patent and its infringement, Defendant has and continues to offer for sale, sell, and use within the United States the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) which are made by a process patented in the '817 Patent during the term of the patent. Accordingly, Plaintiff is entitled to increased damages under 35 U.S.C. § 284 and to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

NINTH CAUSE OF ACTION

(Induced Infringement of the '817 Patent under 35 U.S.C. § 271(b))

237. Orthopaedic Hospital incorporates the foregoing allegations as if fully realleged and restated herein.

238. Upon information and belief, in violation of 35 U.S.C. § 271(b), Defendant has indirectly infringed and is still indirectly infringing the ’817 Patent by actively inducing infringement of the ’817 Patent.

239. Defendant, with knowledge that the manufacturing of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) are made by a process patented by the ’817 Patent, has induced and continues to induce their customers (such as physicians) and end users (such as patients) to directly infringe the ’817 Patent by, for example, specifically instructing such individuals to buy and use the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) within the United States.

240. As further detailed above, Defendant has had active and constructive notice of the ’817 Patent since at least as early as 2015. Accordingly, Defendant has known, should have known or has been willfully blind to the fact that the manufacture of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the ’817 Patent no later than October 13, 2015, the date on which the ’817 Patent issued.

241. Alternatively, as further detailed above, Defendant has had active and constructive notice of the ’817 Patent since at least as early as May 2019. Accordingly, Defendant has known, should have known or has been willfully blind to the fact that the manufacture of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the ’817 Patent no later than May 2019.

242. At minimum, Defendant had actual notice that its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringe one or more claims of the ’817 Patent at least as of July 26, 2019.

243. Upon information and belief, Defendant's customers (such as orthopedic surgeons) and end users (such as patients) directly infringe the '817 Patent when they use within the United States the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) which are made by a process patented in the '817 Patent during the term of the patent.

244. For example, Defendant advertises, and provides pictures and catalogue information about, the Vitelene® implant products on its website for healthcare professionals and patients alike.

245. Defendant also provides a resource for patients to find surgeons who utilize the Vitelene® implant products.

246. Plaintiff has been injured and continues to be injured monetarily and otherwise by Defendant's indirect infringement of the '817 Patent in violation of 35 U.S.C. § 271(b). Defendant is therefore liable to Plaintiff for the damages suffered by Plaintiff.

247. By this action, Plaintiff seeks recovery of its damages pursuant to 35 U.S.C. § 284, including, without limitation, a reasonable royalty.

248. Upon information and belief, Defendant's continuing acts of induced infringement are willful, entitling Plaintiff to increased damages under 35 U.S.C. § 284 and to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

TENTH CAUSE OF ACTION

(Direct Infringement of the '025 Patent under 35 U.S.C. § 271(a))

249. Orthopaedic Hospital incorporates the foregoing allegations as if fully realleged and restated herein.

250. The '025 Patent is valid and enforceable, as it was duly and legally issued by the USPTO.

251. Upon information and belief, in violation of 35 U.S.C. § 271(a), Aesculap has infringed and continues to infringe at least one claim of the '025 Patent, literally and/or under the doctrine of equivalents, by practicing and/or directing and controlling the practice of a method that satisfies one or more claim(s) of the '025 Patent when making and/or directing and controlling the making of Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) in the United States.

252. Specifically, Defendant is responsible for the performance of each step of Claim 1 of the '025 Patent when it manufactures and/or directs and controls the manufacture of any of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof).

253. For example, each step of Claim 1 of the '025 Patent is performed when a Vitilene™ polyethylene liner for the Plasmafit™ Pro Acetabular System is manufactured..

254. Exemplary Claim 1 of the '025 Patent recites the following:

> **[Preamble]** A method for producing a wear-resistant and oxidation-resistant medical implant for a joint prosthesis comprising:
>
> **(1)** providing an oxidation-resistant orthopaedic material comprising a polyethylene;
>
> **(2)** forming the orthopaedic material into an implant for the joint prosthesis;
>
> **(3)** packaging the orthopaedic material after being formed into the implant;
>
> **(4)** sterilizing the orthopaedic material while packaged; and
>
> **(5)** irradiating the orthopaedic material during the method at a total radiation dose of above 5 Mrad to about 25 Mrad so as to crosslink the orthopaedic material, thereby improving its wear resistance, without thermally treating the orthopaedic material to extinguish free radicals in the orthopaedic material during or subsequent to irradiating the orthopaedic material, wherein the orthopaedic material contains an antioxidant rendering it resistant to oxidation caused by free radicals generated by the irradiation.

Claim 1, Preamble

255. To the extent the preamble of Claim 1 of the '025 Patent is a limitation, upon information and belief, Defendant's method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component satisfies such limitation because it produces a wear-resistant and oxidation-resistant medical implant of a joint prosthesis.

256. Specifically, the Vitelene® liner provides a bearing surface of a hip prosthesis with oxidative stability that maintains mechanical properties and resists wear.

Claim 1, Step 1

257. Upon information and belief, Defendant's method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component satisfies Step 1 of Claim 1 of the '025 Patent, because the method comprises a step of providing an oxidation-resistant orthopaedic material comprising a polyethylene.

258. Specifically, Vitamin E is blended with raw polyethylene powder prior to compression molding. The result is a polyethylene material intended for ultimate implantation into a patient's body in the form of an acetabular cup liner component of a hip prosthesis. The material is comprised of polyethylene. And the material is oxidation-resistant.

Claim 1, Step 2

259. Upon information and belief, Defendant's method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component satisfies Step 2 of Claim 1 of the '025 Patent, because the method comprises a step of forming the orthopaedic material into an implant for the joint prosthesis.

260. Specifically, Defendant uses the Vitelene® material to form a Vitelene® acetabular insert implant for a hip prosthesis.

261. Aesculap has stated that its "Vitalene® inserts are manufactured using CNC technology."

> The Vitelene® inserts are manufactured using CNC technology and sterilized with ethylene oxide.

Claim 1, Step 3

262. Upon information and belief, Defendant's method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component satisfies Step 3 of Claim 1 of the '025 Patent, because the method comprises a step of packaging the orthopaedic material after being formed into the implant.

Claim 1, Step 4

263. Upon information and belief, Defendant's method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component satisfies Step 4 of Claim 1 of the '025 Patent, because the method comprises a step of sterilizing the orthopaedic material while packaged.

264. Aesculap has stated in its instructions for use that its "Vitelene Insert implants are provided **sterile**."

265. Aesculap has further stated that its Vitelene® inserts are "sterilized with ethylene oxide."

> The Vitelene® inserts are manufactured using CNC technology and sterilized with ethylene oxide.

Claim 1, Step 5

266. Upon information and belief, Defendant's method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component satisfies Step 5 of Claim 1 of the '025 Patent, because the method comprises a step of irradiating the orthopaedic material at a total radiation dose of above 5 Mrad to about 25 Mrad so as to crosslink the orthopaedic material, without thermally treating the orthopaedic material to extinguish free radicals in the orthopaedic material during or subsequent to irradiating the orthopaedic material.

Claim 1, Step 5 (wherein clause)

267. Defendant's method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component further satisfies the wherein clause of Step 5 of Claim 1 of the '025 Patent, because the Vitelene® material contains an antioxidant rendering it resistant to oxidation caused by free radicals generated by the irradiation of step (II).

268. Specifically, the Vitelene® material contains α-Tocopherol, a type of vitamin E (an antioxidant). Blended with the polyethylene, the α-Tocopherol renders the Vitelene® material resistant to oxidation caused by free radicals generated by the irradiation of step (II).

269. Plaintiff has been and continues to be injured monetarily and otherwise by Defendant's direct infringement of the '025 Patent in violation of 35 U.S.C. § 271(a). Defendant is therefore liable to Plaintiff for the damages suffered by Plaintiff.

270. By this action, Plaintiff seeks recovery of its damages pursuant to 35 U.S.C. § 284, including, without limitation, a reasonable royalty.

271. As further detailed above, Defendant has had active and constructive notice of the '025 Patent since at least as early as 2016. Accordingly, Defendant has known or should have known that the manufacture of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '025 Patent no later than January 26, 2016, the date on which the '025 Patent issued.

272. Alternatively, as further detailed above, Defendant has had active and constructive notice of the '025 Patent since at least as early as May 2019. Accordingly, Defendant has known or should have known that the manufacture of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '025 Patent no later than May 2019.

273. At minimum, Defendant had actual notice that its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringe one or more claims of the '025 Patent at least as of July 26, 2019.

274. Upon information and belief, Defendant's infringement of the '025 Patent has been and continues to be willful. Despite its knowledge of the '025 Patent and its infringement, Defendant has and continues to make, use, offer for sale, and sell the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) in the United States. Accordingly, Plaintiff is entitled to increased damages under 35 U.S.C. § 284 and to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

ELEVENTH CAUSE OF ACTION

(Infringement of the '025 Patent under 35 U.S.C. § 271(g))

275. Orthopaedic Hospital incorporates the foregoing allegations as if fully realleged and restated herein.

276. Upon information and belief, in violation of 35 U.S.C. § 271(g), Defendant has directly infringed and continues to infringe, without authority, consent, right, or license, the '025 Patent by offering to sell, selling, or using within the United States the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) which are made by a process patented in the '025 Patent during the term of the patent.

277. Specifically, and as further detailed above, each of the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) is made by a process that comprises at least each step of Claim 1 of the '025 Patent.

278. Accordingly, Defendant's offers for sale, sales, and use of such Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) are infringing under § 271(g).

279. Plaintiff has been injured and continues to be injured monetarily and otherwise by Defendant's direct infringement of the '025 Patent in violation of 35 U.S.C. § 271(g). Defendant is therefore liable to Plaintiff for the damages suffered by Plaintiff.

280. By this action, Plaintiff seeks recovery of its damages pursuant to 35 U.S.C. § 284, including, without limitation, a reasonable royalty.

281. As further detailed above, Defendant has had active and constructive notice of the '025 Patent since at least as early as 2016. Accordingly, Defendant has known or should have known that the sale of its Vitelene® implant products (and Vitelene® polyethylene component(s)

thereof) infringes one or more claims of the '025 Patent no later than January 26, 2016, the date on which the '025 Patent issued.

282. Alternatively, as further detailed above, Defendant has had active and constructive notice of the '025 Patent since at least as early as May 2019. Accordingly, Defendant has known or should have known that the sale of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '025 Patent no later than May 2019.

283. At minimum, Defendant had actual notice that the sale of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '025 Patent at least as of July 26, 2019.

284. Upon information and belief, Defendant's infringement of the '025 patent has been and continues to be willful. Despite its knowledge of the '025 Patent and its infringement, Defendant has and continue to offer for sale, sell, or use within the United States the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) which are made by a process patented in the '025 Patent during the term of the patent. Accordingly, Plaintiff is entitled to increased damages under 35 U.S.C. § 284 and to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

TWELFTH CAUSE OF ACTION

(Induced Infringement of the '025 Patent under 35 U.S.C. § 271(b))

285. Orthopaedic Hospital incorporates the foregoing allegations as if fully realleged and restated herein.

286. Upon information and belief, in violation of 35 U.S.C. § 271(b), Defendant has indirectly infringed and is still indirectly infringing the '025 Patent by actively inducing infringement of the '025 Patent.

287. Defendant, with knowledge that the manufacturing of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) are made by a process patented by the '025 Patent, has induced and continues to induce its customers (such as physicians) and end users (such as patients) to directly infringe the '025 Patent by, for example, specifically instructing such individuals to use the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) within the United States.

288. As further detailed above, Defendant has had active and constructive notice of the '025 Patent since at least as early as 2016. Accordingly, Defendant has known, should have known or has been willfully blind to the fact that the manufacture of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringe one or more claims of the '025 Patent no later than January 26, 2016, the date on which the '025 Patent issued.

289. Alternatively, as further detailed above, Defendant has had active and constructive notice of the '025 Patent since at least as early as May 2019. Accordingly, Defendant has known, should have known or has been willfully blind to the fact that the manufacture of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '025 Patent no later than May 2019.

290. At minimum, Defendant had actual notice that its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringe one or more claims of the '025 Patent at least as of July 26, 2019.

291. Upon information and belief, Defendant's customers (such as orthopedic surgeons) and end users (such as patients) directly infringe the '025 Patent when they use within the United States the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) which are made by a process patented in the '025 Patent during the term of the patent.

292. For example, Defendant advertises, and provides pictures and catalogue information about, the Vitelene® implant products on its website for healthcare professionals and patients alike.

293. Defendant also provides a resource for patients to find surgeons who utilize the Vitelene® implant products.

294. Plaintiff has been injured and continues to be injured monetarily and otherwise by Defendant's indirect infringement of the '025 Patent in violation of 35 U.S.C. § 271(b). Defendant is therefore liable to Plaintiff for the damages suffered by Plaintiff.

295. By this action, Plaintiff seeks recovery of its damages pursuant to 35 U.S.C. § 284, including, without limitation, a reasonable royalty.

296. Upon information and belief, Defendant's continuing acts of induced infringement are willful, entitling Plaintiff to increased damages under 35 U.S.C. § 284 and to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

THIRTEENTH CAUSE OF ACTION

(Direct Infringement of the '028 Patent under 35 U.S.C. § 271(a))

297. Orthopaedic Hospital incorporates the foregoing allegations as if fully realleged and restated herein.

298. The '028 Patent is valid and enforceable, as it was duly and legally issued by the USPTO.

299. Upon information and belief, in violation of 35 U.S.C. § 271(a), Aesculap has infringed and continues to infringe at least one claim of the '028 Patent, literally and/or under the doctrine of equivalents, by practicing and/or directing and controlling the practice of a method that satisfies one or more claim(s) of the '028 Patent when making and/or directing and controlling the

making of Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) in the United States.

300. Specifically, Defendant is responsible for the performance of each step of Claim 1 of the '028 Patent when it manufactures and/or directs and controls the manufacture of any of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof).

301. For example, each step of Claim 1 of the '028 Patent is performed when a Vitilene™ polyethylene liner for the Plasmafit™ Pro Acetabular System is manufactured.

302. Exemplary Claim 1 of the '028 Patent recites the following:

> **[Preamble]** A method for producing a wear-resistant and oxidation resistant medical implant of a joint prosthesis, said method comprising the steps of:
>
> **(I)** providing an oxidation-resistant medical implant of a joint prosthesis comprising a polyethylene component; and
>
> **(II)** irradiating the oxidation-resistant medical implant at a radiation dose of above 5 Mrad to about 25 Mrad so as to crosslink the implant thereby improving its wear resistance, without thermally treating the implant to extinguish free radicals in the irradiated and crosslinked implant during or subsequent to irradiating the oxidation-resistant implant;
>
> wherein the oxidation-resistant implant contains an antioxidant rendering it resistant to oxidation caused by free radicals generated by the irradiation of step (II); and the irradiated oxidation-resistant implant possesses a gel content of between about 95% to about 99%.

Claim 1, Preamble

303. To the extent the preamble of Claim 1 of the '028 Patent is a limitation, upon information and belief, Defendant's method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component satisfies such limitation because it produces a wear-resistant and oxidation-resistant medical implant of a joint prosthesis.

304. Specifically, the Vitelene® liner provides a bearing surface of a hip prosthesis with oxidative stability that maintains mechanical properties and resists wear.

Claim 1, Step I

305. Upon information and belief, Defendant's method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component satisfies Step I of Claim 1 of the '028 Patent, because the method comprises a step of providing an oxidation-resistant medical implant of a joint prosthesis comprising a polyethylene component.

306. Specifically, Vitamin E is blended with raw polyethylene powder prior to compression molding. The result is a polyethylene material intended for ultimate implantation into a patient's body in the form of an acetabular cup liner component of a hip prosthesis. The component is comprised of polyethylene. And the component is oxidation-resistant.

Claim 1, Step II

307. Upon information and belief, Defendant's method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component satisfies Step II of Claim 1 of the '028 Patent, because the method comprises a step of irradiating the medical implant at a radiation dose of above 5 Mrad to about 25 Mrad so as to crosslink the implant thereby improving its wear resistance, without thermally treating the implant to extinguish free radicals in the irradiated and crosslinked implant during or subsequent to irradiating the oxidation-resistant implant.

Claim 1, Step II (wherein clause)

308. Upon information and belief, Defendant's method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component

further satisfies the wherein clause of Step II of Claim 1 of the '028 Patent, because the Vitelene® component contains an antioxidant rendering it resistant to oxidation caused by free radicals generated by the irradiation of step (II).

309. Specifically, each Vitelene® component contains α-Tocopherol, a type of vitamin E (an antioxidant). Blended with the polyethylene, the α-Tocopherol renders the Vitelene® component resistant to oxidation caused by free radicals generated by the irradiation of step (II).

310. Upon information and belief, Defendant's method of manufacturing Vitelene® polyethylene components and all products incorporating a Vitelene® polyethylene component further satisfies the wherein clause of Step II of Claim 1 of the '028 Patent, because, upon information and belief, the irradiated Vitelene® component possess a gel content of about 95% to about 99%.

311. Plaintiff has been and continues to be injured monetarily and otherwise by Defendant's direct infringement of the '028 Patent in violation of 35 U.S.C. § 271(a). Defendant is therefore liable to Plaintiff for the damages suffered by Plaintiff.

312. By this action, Plaintiff seeks recovery of its damages pursuant to 35 U.S.C. § 284, including, without limitation, a reasonable royalty.

313. As further detailed above, Defendant has had active and constructive notice of the '028 Patent since at least as early as 2016. Accordingly, Defendant has known or should have known that the manufacture of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '028 Patent no later than April 5, 2016, the date on which the '028 Patent issued.

314. Alternatively, as further detailed above, Defendant has had active and constructive notice of the '028 Patent since at least as early as May 2019. Accordingly, Defendant has known or should have known that the manufacture of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '028 Patent no later than May 2019.

315. At minimum, Defendant had actual notice that its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringe one or more claims of the '028 Patent at least as of July 26, 2019.

316. Upon information and belief, Defendant's infringement of the '028 Patent has been and continues to be willful. Despite its knowledge of the '028 Patent and its infringement, Defendant has and continues to make, use, offer for sale and sell the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) in the United States. Accordingly, Plaintiff is entitled to increased damages under 35 U.S.C. § 284 and to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

FOURTEENTH CAUSE OF ACTION

(Infringement of the '028 Patent under 35 U.S.C. § 271(g))

317. Orthopaedic Hospital incorporates the foregoing allegations as if fully realleged and restated herein.

318. Upon information and belief, in violation of 35 U.S.C. § 271(g), Defendant has directly infringed and continues to infringe, without authority, consent, right, or license, the '028 Patent by offering to sell, selling, or using within the United States the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) which are made by a process patented in the '028 Patent during the term of the patent.

319. Specifically, and as further detailed above, each of the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) is made by a process that comprises at least each step of Claim 1 of the '028 Patent.

320. Accordingly, Defendant's offers for sale, sales, and use of such Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) are infringing under § 271(g).

321. Plaintiff has been injured and continues to be injured monetarily and otherwise by Defendant's direct infringement of the '028 Patent in violation of 35 U.S.C. § 271(g). Defendant is therefore liable to Plaintiff for the damages suffered by Plaintiff.

322. By this action, Plaintiff seeks recovery of its damages pursuant to 35 U.S.C. § 284, including, without limitation, a reasonable royalty.

323. As further detailed above, Defendant has had active and constructive notice of the '028 Patent since at least as early as 2016. Accordingly, Defendant has known or should have known that the sale of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '028 Patent no later than April 5, 2016, the date on which the '028 Patent issued.

324. Alternatively, as further detailed above, Defendant has had active and constructive notice of the '028 Patent since at least as early as May 2019. Accordingly, Defendant has known or should have known that the sale of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '028 Patent no later than May 2019.

325. At minimum, Defendant had actual notice that the sale of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the '028 Patent at least as of July 26, 2019.

326. Upon information and belief, Defendant's infringement of the '028 patent has been and continues to be willful. Despite its knowledge of the '028 Patent and its infringement, Defendant has and continues to offer for sale, sell, and use within the United States the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) which are made by a process patented in the '028 Patent during the term of the patent. Accordingly, Plaintiff is entitled to increased damages under 35 U.S.C. § 284 and to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

FIFTEENTH CAUSE OF ACTION

(Induced Infringement of the '028 Patent under 35 U.S.C. § 271(b))

327. Orthopaedic Hospital incorporates the foregoing allegations as if fully realleged and restated herein.

328. Upon information and belief, in violation of 35 U.S.C. § 271(b), Defendant has indirectly infringed and is still indirectly infringing the '028 Patent by actively inducing infringement of the '028 Patent.

329. Defendant, with knowledge that the manufacturing of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) are made by a process patented by the '028 Patent, has induced and continues to induce its customers (such as physicians) and end users (such as patients) to directly infringe the '028 Patent by, for example specifically instructing such individuals to use the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) within the United States.

330. As further detailed above, Defendant has had active and constructive notice of the '028 Patent since at least as early as 2016. Accordingly, Defendant has known, should have known or has been willfully blind to the fact that the manufacture of its Vitelene® implant products (and

Vitelene® polyethylene component(s) thereof) infringes one or more claims of the ’028 Patent no later than April 5, 2016, the date on which the ’028 Patent issued.

331. Alternatively, as further detailed above, Defendant has had active and constructive notice of the ’028 Patent since at least as early as May 2019. Accordingly, Defendant has known, should have known or has been willfully blind to the fact that the manufacture of its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringes one or more claims of the ’028 Patent no later than May 2019.

332. At minimum, Defendant had actual notice that its Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) infringe one or more claims of the ’028 Patent at least as of July 26, 2019.

333. Upon information and belief, Defendant’s customers (such as orthopedic surgeons) and end users (such as patients) directly infringe the ’028 Patent when they buy and use within the United States the Vitelene® implant products (and Vitelene® polyethylene component(s) thereof) which are made by a process patented in the ’028 Patent during the term of the patent.

334. For example, Defendant advertises, and provides pictures and catalogue information about, the Vitelene® implant products on its website for healthcare professionals and patients alike.

335. Defendant also provides a resource for patients to find surgeons who utilize the Vitelene® implant products.

336. Plaintiff has been injured and continues to be injured monetarily and otherwise by Defendant’s indirect infringement of the ’028 Patent in violation of 35 U.S.C. § 271(b). Defendant is therefore liable to Plaintiff for the damages suffered by Plaintiff.

337. By this action, Plaintiff seeks recovery of its damages pursuant to 35 U.S.C. § 284, including, without limitation, a reasonable royalty.

338. Upon information and belief, Defendant's continuing acts of induced infringement are willful, entitling Plaintiff to increased damages under 35 U.S.C. § 284 and to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendant, and respectfully requests the following relief:

1. A judgment that Defendant has infringed and is infringing directly and/or indirectly one or more claims of the '347 Patent;

2. A judgment that Defendant has infringed and is infringing directly and/or indirectly one or more claims of the '710 Patent;

3. A judgment that Defendant has infringed and is infringing directly and/or indirectly one or more claims of the '817 Patent;

4. A judgment that Defendant has infringed and is infringing directly and/or indirectly one or more claims of the '025 Patent;

5. A judgment that Defendant has infringed and is infringing directly and/or indirectly one or more claims of the '028 Patent;

6. An award of damages or other monetary relief, including but not limited to, costs and pre- and post-judgment interest, to Plaintiff;

7. A declaration that Defendant's infringement is willful and deliberate and an increase to the award of damages of three times the amount found or assessed by the Court, pursuant to 35 U.S.C. § 284; and

8. Such other and further relief as the Court deems just and appropriate, including but not limited to, a determination that this is an exceptional case pursuant to 35 U.S.C. § 285 and an award of attorneys' fees and costs to Plaintiff in this action.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff demands a jury trial as to all matters so triable.

MCDERMOTT WILL & EMERY LLP

/s/ *Ashley R. Altschuler*
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October 9, 2020

AO 120 (Rev. 08/10)

TO:	**Mail Stop 8** **Director of the U.S. Patent and Trademark Office** **P.O. Box 1450** **Alexandria, VA 22313-1450**	**REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK**

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court Delaware on the following

☐ Trademarks or ☑ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
	10/9/2020	Delaware

PLAINTIFF	DEFENDANT
ORTHOPAEDIC HOSPITAL d/b/a Orthopaedic Institute For Children	Aesculap Implant Systems, LLC

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	8,796,347	8/5/2014	Orthopaedic Hospital
2	8,658,710	2/25/2014	Orthopaedic Hospital
3	9,155,817	10/13/2015	Orthopaedic Hospital
4	9,242,025	1/26/2016	Orthopaedic Hospital
5	9,302,028	4/5/2016	Orthopaedic Hospital

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE

Copy 1—Upon initiation of action, mail this copy to Director **Copy 3—Upon termination of action, mail this copy to Director**
Copy 2—Upon filing document adding patent(s), mail this copy to Director **Copy 4—Case file copy**